

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE**

**IN RE: VALSARTAN, LOSARTAN,
AND IRBESARTAN PRODUCTS
LIABILITY LITIGATION**

This Document Relates to All Actions

MDL No. 2875

Honorable Robert R. Kugler,
District Court Judge

Oral Argument Requested

**DEFENDANTS' MEMORANDUM OF LAW IN OPPOSITION TO
PLAINTIFFS' MOTION TO STRIKE DEFENDANTS' EXPERT
MICHAEL B. BOTTORFF'S PURPORTEDLY
"NEW AND ALTERED" GENERAL CAUSATION OPINIONS**

TABLE OF CONTENTS

INTRODUCTION.....	1
LEGAL STANDARD	3
ARGUMENT	4
I. DR. BOTTORFF'S CLASS CERTIFICATION REPORT DOES NOT OFFER NEW OR ALTERED GENERAL CAUSATION OPINIONS.....	4
A. Dr. Bottorff Has Not Offered a New Opinion on the Bioavailability of NDMA/NDEA.....	5
B. Dr. Bottorff's Opinion About Human DNA Repair Mechanisms Is Not New.....	8
II. STRIKING ANY PORTION OF DR. BOTTORFF'S REPORT WOULD BE A HARSH AND DISPROPORTIONATE SANCTION	9
CONCLUSION.....	10

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Bridgestone Sports Co. Ltd. v. Acushnet Co.</i> , Civ. No. 05-132-JJF, 2007 U.S. Dist LEXIS 11370 (D. Del. Feb. 15, 2007).....	3
<i>Dow Chem. Co. v. Nova Chems. Corp.</i> , 2010 U.S. Dist. LEXIS 50101, *4, *8 (D. Del. May 20, 2010).....	9
<i>Diawara v. United States</i> , 2020 U.S. Dist. LEXIS 197070, *14 (E.D. Pa Oct. 22, 2020).....	4
<i>Metavante Corp. v. Emigrant Sav. Bank</i> , 619 F.3d 748, 762 (7th Cir. 2010).....	4
<i>Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.</i> , 585 F. Supp. 2d 568 (D. Del. 2008).....	2, 4, 8
<i>United States v. Barrett</i> , 117 F. App'x 216, 219 (3d Cir. 2004)	4
<i>Vandenbraak v. Alfieri</i> , No. CIV.A. 01-482KAJ, 2005 U.S. Dist. LEXIS 9882, at *3 (D. Del. May 25, 2005).....	5
Other Authorities	
Federal Rule of Evidence 702.....	3

Defendants' Executive Committee, on behalf of the undersigned Defendants, submit this memorandum of law in opposition to Plaintiffs' Motion to Strike Defendants' Expert Michael B. Bottorff's purportedly "new and altered" general causation opinions and state as follows:

INTRODUCTION

The gist of Plaintiffs' four-page motion is that because a few isolated portions of Dr. Bottorff's Class Certification Report¹ addressing causation issues do not regurgitate word-for-word the language used in his General Causation Report, those sections somehow constitute "new" general causation opinions that should be stricken. But the statements challenged by Plaintiffs are entirely consistent with Dr. Bottorff's opinions in his General Causation Report and, at most, elaborate on them. Plaintiffs' motion is therefore frivolous.

Plaintiffs first argue that the statement in Dr. Bottorff's Class Certification Report that the liver "prevent[s] NDMA/NDEA exposure to other tissues and organs" is at odds with his general causation statement that the organ "minimiz[es]

¹ Defendants will refer to the Report of Michael Bottorff, Pharm. D., dated January 12, 2022, [ECF [2009-15](#)], as Dr. Bottorff's ("Class Certification Report" or "Class Cert. Rep."). Defendants will refer to the Report of Michael Bottorff Pharm.D., dated August 2, 2021, [ECF [1789-2](#)], as Dr. Bottorff's ("General Causation Report" or "Causation Rep."). Defendants will refer to the deposition of Michael Bottorff, Pharm. D., taken on September 16, 2021, [ECF [1789-3](#)] as Dr. Bottorff's ("General Causation Deposition" or "Causation Dep."). Defendants will refer to the deposition of Michael Bottorff, Pharm.D., taken on March 25, 2022, attached hereto as **Exhibit A**, as Dr. Bottorff's ("Class Certification Deposition" or "Class Cert. Dep.").

exposure to other tissues and organs.” (Pls.’ Mot. at 3.) But the two statements are not remotely in tension and comport with Dr. Bottorff’s opinion (long known to Plaintiffs) that the liver will almost completely metabolize the level of NDMA contained in the affected valsartan tablets, posing no increased risk to any downstream organs.

Plaintiffs also challenge the statement in Dr. Bottorff’s Class Certification Report that “DNA repair mechanisms in humans can be as much as 10x higher than rats[.]” (Pls.’ Mot. at 3.) But that statement is merely a “reasonable synthesis and/or elaboration of the [DNA repair] opinions contained in [Dr. Bottorff’s] [original] report.” *Power Integrations, Inc. v. Fairchild Semiconductor Int’l, Inc.*, 585 F. Supp. 2d 568, 581 (D. Del. 2008). Indeed, the statement is based on a study that was cited in Dr. Bottorff’s General Causation Report and helps explain why Plaintiffs’ requested medical monitoring is neither appropriate nor justified. In short, Plaintiffs are unable to identify even a single “new” general causation opinion in Dr. Bottorff’s Class Certification Report, which forecloses Plaintiffs’ motion.

In any event, even assuming that the language highlighted by Plaintiffs were procedurally improper (and it is not), Plaintiffs have not come close to justifying the extreme sanction of exclusion. Imposition of such a sanction generally requires intentional misconduct, and not even Plaintiffs suggest (much less attempt to demonstrate) that anything either Dr. Bottorff or Defendants did rises to that

standard. Plaintiffs' requested exclusion would be especially improper given that they have had ample opportunity to probe the expert at his Class Certification Deposition, belying any suggestion of prejudice.

For these reasons, as detailed below, the Court should deny Plaintiffs' motion to strike.

LEGAL STANDARD

“The exclusion of critical evidence is considered an *extreme sanction*, not normally to be imposed absent a showing of willful deception or flagrant disregard of a court order by the proponent of the evidence.” *Bridgestone Sports Co. Ltd. v. Acushnet Co.*, Civ. No. 05-132-JJF, 2007 U.S. Dist LEXIS 11370, *10 (D. Del. Feb. 15, 2007) (quoting *In re Paoli R.R. Yard PCB Litg.*, 35 F.3d 717, 749 (3d Cir. 1994) (emphasis added)). Federal Rule of Evidence 702 provides that a witness who is “qualified as an expert by knowledge, skill, experience, training, or education” may offer opinions in a case if (i) the expert’s “scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue”; (ii) “the testimony is based on sufficient facts or data”; (iii) “the testimony is the product of reliable principles and methods”; and (iv) “the expert has reliably applied the principles and methods to the facts of the case.” This Court has already ruled that Dr. Bottorff and his opinions meet these requirements. *See Daubert Order 2* [ECF [1974](#)] at 3.

ARGUMENT

I. DR. BOTTORFF'S CLASS CERTIFICATION REPORT DOES NOT OFFER NEW OR ALTERED GENERAL CAUSATION OPINIONS

“The purpose of . . . [expert] reports is not to replicate every word that the expert might say on the stand. It is instead to convey the substance of the expert’s opinion . . . so that the opponent will be ready to rebut, to cross-examine, and to offer a competing expert if necessary.” *Metavante Corp. v. Emigrant Sav. Bank*, 619 F.3d 748, 762 (7th Cir. 2010) (quoting *Walsh v. Chez*, 583 F.3d 990, 994 (7th Cir. 2009) (alteration and omission in original)). Accordingly, an expert need not demonstrate verbatim consistency with her expert report; rather, she is free to “synthes[ize] and/or elaborate[e] [on] the opinions contained in [her] . . . report[.]” *Power Integrations, Inc.*, 585 F. Supp. 2d at 581; *see, e.g., Id.* at 581-82 (noting that verbatim consistency with the expert’s report is not required and stating “the Court does not understand Mr. Shields’ trial testimony to be inconsistent with th[e] premise [of report], even though the precise wording of his testimony may have differed from the wording used in the expert report.”); *see also United States v. Barrett*, 117 F. App’x 216, 219 (3d Cir. 2004) (district court properly admitted expert testimony that was a “logical and reasonable inference from the language contained in the [expert’s] report”); *Diawara v. United States*, 2020 U.S. Dist. LEXIS 197070, *14 (E.D. Pa Oct. 22, 2020) (denying motion *in limine* to exclude expert testimony not included in expert report because expert offered the basis for opinion during deposition and

there was no surprise to opposing party); *Vandenbraak v. Alfieri*, No. CIV.A. 01-482KAJ, 2005 U.S. Dist. LEXIS 9882, at *3 (D. Del. May 25, 2005) (The purpose of Rule 26(a)(2)(b) is to “protect opposing parties from unfair surprise”). Dr. Bottorff’s class-certification opinion addressing the bioavailability of NDMA/NDEA and his class-certification opinion regarding DNA repair mechanisms easily satisfy this liberal standard because they are fully consistent with his original general causation opinions and merely elaborate on those conclusions.

A. Dr. Bottorff Has Not Offered a New Opinion on the Bioavailability of NDMA/NDEA.

Plaintiffs argue that Dr. Bottorff’s *opinion* on the bioavailability² of NDMA/NDEA in his Class Certification Report is somehow “new” or “altered” because the *explanation* Dr. Bottorff offered for this opinion in his General Causation Report used a different word than that employed in his Class Certification Report. (*See* Pls.’ Mot. at 3.) In particular, Plaintiffs object that while Dr. Bottorff stated in his General Causation Report that NDMA/NDEA in “[s]maller oral doses are metabolized in the liver almost completely, **minimizing** exposure to other tissues and organs” (*id.* (quoting ECF [1712-5](#))), his Class Certification Report states that such doses are “metabolized in the liver almost completely, **preventing** exposure to other tissues and organs.” (*Id.* (quoting Ex., B).) But there is no meaningful

² “Bioavailability” is the concept of whether and to what degree ingested drugs or chemicals pass through the liver into systemic circulation.

difference between the words “preventing” and “minimizing” when used in the context of reducing a risk, as Dr. Bottorff uses these words here.³ A comparison of the relevant portions of the reports further illustrates this point.

Smaller oral doses are metabolized in the liver almost completely, minimizing exposure to other tissues and organs. Thus, metabolism of NDMA/NDEA that is ingested orally—such as the trace NDMA/NDEA found in orally ingested valsartan—is a classic example of first-pass metabolism: at low oral doses, like the trace amounts found in valsartan products, **metabolism occurs almost entirely during the compound’s first pass through the liver, before it ever reaches systemic circulation.**

(Causation Rep. at 28) (Emphasis added).

Oral doses at the levels detected in generic valsartan at issue in this litigation are metabolized in the liver almost completely, preventing exposure to other tissues and organs. In other words, metabolism of NDMA/NDEA that is ingested orally—such as the NDMA/NDEA amounts found in orally ingested valsartan—is a classic example of first-pass metabolism: at oral doses, in the amounts found in valsartan products, **metabolism occurs almost entirely during the compound’s first pass through the liver, before it ever reaches systemic circulation.**

(Class Cert. Rep. at 48) (Emphasis added). These statements are wholly consistent, and nothing about them renders the bioavailability opinion Dr. Bottorff offers in his

³ **TRANSITIVE VERB:** If you **minimize** a risk, problem, or unpleasant situation, you reduce it to the lowest possible level, or **prevent it** from increasing beyond that level. See *Definition of ‘Minimize’*, Collins English Dictionary, <https://www.collinsdictionary.com/us/dictionary/english/minimize> (last visited May 20, 2022).

Class Certification Report “new or altered.”

Plaintiffs also complain that Dr. Bottorff’s Class Certification Report includes the statement that “‘NDMA/NDEA in valsartan will not reach systemic circulation,’ which was absent in [the expert’s] General Causation Report.” (Pls.’ Mot. at 3 (quoting Ex. B.).) But the challenged statement is just another way of explaining Dr. Bottorff’s general causation opinion—i.e., that “the level of NDMA and/or NDEA found in the valsartan drugs at issue **would not be circulated beyond the liver** and would not reach organs that are not part of the digestion/metabolism process.” (General Causation Report [ECF [1789-2](#)] at 63 (emphasis added).) In fact, Plaintiffs specifically questioned Dr. Bottorff during his General Causation Deposition about his opinion that the NDMA in valsartan would not reach systemic circulation:

Q: Okay. And you would never expect to see NDMA in the blood of a human, correct, because you believe that the liver should be able to handle all of it?

A: Well, let me – let me qualify that by saying that **at the amounts that were found in the – of NDMA and NDEA in the valsartan tablets, I would not expect that to reach the systemic circulation at all based upon first-pass metabolism.**

(General Causation Dep. [ECF [1789-3](#)] 152:12-23 (emphasis added).) In short, Dr. Bottorff has consistently opined that NDMA/NDEA will not reach systemic circulation or organs downstream from the liver, irrespective of the specific words he used in his General Causation Report. Accordingly, there is no basis to strike this opinion as somehow “new.”

B. Dr. Bottorff's Opinion About Human DNA Repair Mechanisms Is Not New.

Plaintiffs also contend that Dr. Bottorff's statement that human DNA repair mechanisms are more active than the DNA repair mechanisms of rats is a new general causation opinion. *See* Plaintiffs' Motion to Strike [ECF [2043](#)] at 4. This is similarly inaccurate. Dr. Bottorff has always opined that DNA repair of the known adducts formed by NDMA metabolites is a protective mechanism that prevents NDMA exposure from becoming cancer in the liver or elsewhere. *See* General Causation Dep. [ECF [1789-3](#)] 224:1-225:3. That opinion relied on a series of animal studies, including a paper explaining that the reason why doses of NDMA as “low as .1 and 1/0 mg/kg/day do not appear to exceed the capacity of the liver to metabolize the potential carcinogen” “may be due to the presence in the liver of a carcinogenic ‘surveillance’ system that removes 06-methylguanine from DNA prior to carcinogenesis.” General Causation Report [ECF [1789-2](#)] at 33.

The statement at issue in Dr. Bottorff's Class Certification Report—that “DNA repair mechanisms in humans can be as much as 10x higher than rats” (Pls.' Mot. At 3)—is a “reasonable synthesis and/or elaboration of the opinions contained in the expert's [original] report.” *Power Integrations, Inc.*, 585 F. Supp. 2d at 581. Indeed, as Dr. Bottorff explained at his Class Certification Deposition, although he “may not have” included that quantification in his General Causation Report, he “quantified it here from a statement made in [some] of the [Pegg] articles” cited in

that very report. Bottorff Class Cert. Dep. 24:8-10 (emphasis added). Notably, even Plaintiffs' own expert agrees that "human DNA repair [capacity] *greatly exceeds* that of a rat[.]" Panigrahy Dep. [ECF [1716-4](#)] 464:24-465 (emphasis added). Accordingly, there is nothing new about Dr. Bottorff's opinion, and it should not be stricken.

This is all the more true given that Dr. Bottorff's quantification is uniquely relevant to the certifiability of Plaintiffs' proposed medical monitoring class. As Dr. Bottorff explained at his most recent deposition, "DNA repair mechanisms" limit the exposure of NDMA and NDEA to the liver, meaning that "there's no exposure enough to downstream organs to justify medical monitoring[.]" Bottorff Class Cert Dep. 24:11-25:7. In short, not only is Dr. Bottorff's opinion regarding human DNA repair mechanisms entirely consistent with his General Causation Report, but he was fully justified in elaborating on it at the class certification stage in light of Plaintiffs' medical monitoring proposals.

II. STRIKING ANY PORTION OF DR. BOTTORFF'S REPORT WOULD BE A HARSH AND DISPROPORTIONATE SANCTION

Even if Dr. Bottorff had revised his opinions, it would still be inappropriate to strike portions of his report. Exclusion of critical evidence is "'considered an extreme sanction, not normally to be imposed absent a showing of willful deception or flagrant disregard of a court order by the proponent of the evidence.'" *Dow Chem. Co. v. Nova Chems. Corp.*, 2010 U.S. Dist. LEXIS 50101, *4, *8 (D. Del. May 20,

2010) (“the Court will not strike the declarations of Dow’s experts because they consist of consistent and appropriate elaborations of prior opinions and statements”). Plaintiffs have not even attempted to make the required showing here. Indeed, Plaintiffs **have cited no law** in support of their motion to strike, much less any that supports the extreme relief being requested here. For this reason as well, the Court should deny Plaintiffs’ motion.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court deny Plaintiffs’ Motion to Strike Defendants’ Expert Michael B. Bottorff’s purportedly “new and altered” general causation opinions.

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Respectfully Submitted:

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I hereby certify that on June 2, 2022, I caused a copy of the foregoing document to be served on all counsel of record via CM/ECF.

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